SEP 1 4 2000

K002570

Bio-logic One Bio-logic Plaza Mundelein, Illinois 60060-3700 1-800-323-8326 Fax: 847-949-8615

SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning this Device Modification to Bio-logic Ceegraph for Netlink is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

PREPARED BY: Bio-logic Systems Corp
One Bio-logic Plaza
Mundelein, IL 60060

TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: August 15, 2000

NAME OF DEVICE: Bio-logic Ceegraph Netlink.

COMMON NAME: Digital EEG Recorder.

CLASSIFICATION NAME: Electroencephalograph (per CFR 882.1400).

PREDICATE DEVICE: Bio-logic Ceegraph 32-Channel Digital EEG System, 510(k) #K933233, and Ceegraph 128-Channel Digital EEG System, 510(k) #973883.

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DESCRIPTION OF THE DEVICE:

The Netlink system patient connection module (headbox) consists of a molded plastic enclosure approximately 10" x 7" x 2.25" in size and weighing approximately 36 oz. It can be configured to perform up to 40 channel data recordings, having 32 AC channels and 8 DC channels. Power to the box is supplied with an external medical-grade power supply, which supplies regulated 5 volts DC to a connector at the rear of the box. Communication to the host computer is performed through a standard Ethernet interface connector capable of running at data rates up to 10 MHz (10 base-T). There are 32 touch-proof "safety jack" electrode connections on the top surface of the headbox, along with reference and ground touch-proof jacks. Also, there are 8 additional 3.5 mm jacks for DC interfaces to external transducers on the side of the box. Other connectors (Ethernet, photic strobe out, sync in, etc.) are located on the rear of the box. Also, there is a 50-pin connector to allow use of the smaller auxiliary patient connection modules which can be carried or worn by the patient.

The Netlink system consists of a microprocessor board, a digital interface board, two (2) 16-channel analog boards and an 8-channel DC board. The analog boards are very similar in function to the 16-channel analog boards used in the patient connection module (headbox) of the 32-Channel Predicate Device. These boards provide patient isolation and signal amplification. The 50-pin auxiliary connector is the same as the auxiliary connector of both Predicate Devices. This allows the use of existing patient connection hardware, such as electrode arrays, the 32-channel" electrode connection panel called the "quick disconnect box", and the "Quick-Tilt" headbox which can be comfortably worn by a patient for long periods of time. The microprocessor board contains program and data memory and control functions for reading the analog data, converting it to digital, and communicating it to the host computer through the Ethernet cable. The digital interface board contains the interface to the A/D converters and the communications hardware. Additional features of the Netlink headbox include an array of LED's to facilitate electrode impedance measurements, an electrode continuity tester, programmable sampling rates, and dedicated pushbuttons to activate collection and impedance measurement.

INTENDED USE:

The Bio-logic Ceegraph EEG product family is indicated for use in the recording and analysis of EEG tests. Typical routine EEG tests are 20-30 minutes in duration, but the Ceegraph system can also be used for longer tests, including continuous long-term EEG monitoring with patient video. In general, EEG testing is indicated for use whenever it is necessary to measure and record a patient's electrophysiological activity, including the electrical activity of the brain, by attaching multiple electrodes at various locations on the body.

The Netlink Data Recording system has a similar intended use to that of the currently-marketed 32 and 128 channel Ceegraph recording systems. It can be used for patients of all ages, from newborn infants through adults, to and including geriatric patients.

The use of the Bio-logic Ceegraph EEG family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

PATIENT POPULATION: Adults, children and infants.

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SAFETY AND EFFECTIVENESS SUMMARY

To establish the safety and effectiveness of Netlink, this modification to Bio-logic Ceegraph was designed and incorporated into the product line in accordance with the Bio-logic internal Product Development procedures which are intended to meet ISO-9001 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis for the Ceegraph Netlink product was performed using the Fault Tree analysis (FTA) approach, and a detailed Risk Assessment was written in accordance with EN-1441, the International Standard for Hazard/Risk analysis.

The Ceegraph Netlink patient-connection hardware utilizes many of the same design principles and circuit designs as are used in the Bio-logic Ceegraph Predicate Devices. There are no newly-introduced hardware-related methods by which the patient can be harmed or injured through the use of this device. The same patient isolation methods are used in all products. The Netlink utilizes a medical-grade power supply, as does the 128-Channel Predicate Device. The 32-channel Predicate Device hardware is powered from the host computer, which is always used with an approved isolation transformer. Direct hardware control of all Netlink functions is provided from the embedded microprocessor and its program code located inside the Netlink package, instead of directly from the host computer program. By distributing the hardware-specific functions to the Netlink headbox, the Windows-based Ceegraph IV host computer program has fewer real-time demands, and performance and reliability are improved.

The Ceegraph IV Netlink software does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program "recommendations" are subject to review by the EEG Technologist or Physician, and may be modified, overridden or deleted as determined by a qualified user. The program provides additional functionality to allow the qualified user to review all raw data collected and perform other data analysis to suit his or her requirements.

The chart on the next page provides a summary comparison of the technological characteristics of the new modified device relative to the predicate devices. This is to demonstrate that this new Ceegraph Netlink device has no significant differences which would adversely affect product safety and effectiveness.

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Parameter for comparison	Similarity or Difference – 32-Channel Predicate Device	Similarity or Difference – 128-Channel Predicate Device
Intended Use	No differences.	No differences.
Population	No differences.	No differences.
Recording capacity	Netlink has up to 40-channel capacity with 8 DC channels. This Predicate Device has only 32 channels, 2 of which can be configured as either AC or DC.	This Predicate Device has up to 128 channels for AC "head" channels, but no DC channels.
Host Computer to Headbox Connection.	Netlink uses an industry-standard Ethernet interface. This Predicate Device uses a 25-wire serial interface cable.	No differences.
Computer Control Software	Netlink uses the same Ceegraph IV software as this Predicate Device, with minor additions to accommodate control of the new hardware.	Netlink uses the same Ceegraph IV software as this Predicate Device, with minor additions to accommodate control of the new hardware.
Patient information and tracking	No differences.	No differences.
Safety Characteristics	No differences. The basic patient connection and isolation circuits are the same for both products.	No differences. The basic patient connection and isolation circuits are the same for both products.
Data Quality	No differences.	No differences.
Patient Connections	Very similar. Both devices arrange the safety jack touch-proof electrode connections in a "head" shape for ease of use.	This Predicate Device requires the use of one or more external "quick disconnect" patient connection modules. There are no electrode jacks located directly on the 128-Channel hardware.
Impedance display on headbox.	Not provided for on this Predicate Device	Not provided for on this Predicate Device
Physical Characteristics	This Predicate Device is slightly smaller than Netlink.	This Predicate Device is larger than Netlink.
Product Labeling	Similar safety, information and warning labels. Different size and shape of box requires some different labels.	Similar safety, information and warning labels. Different size and shape of box requires some different labels.
Anatomical sites	No differences.	No differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2000

Mr. Norman E. Brunner
Vice President of Research and Development
Bio-Logic Systems Corporation
One Bio-Logic Plaza
Mundelein, Illinois 60060

Re: K002570
Trade Name: Bio-logic Ceegraph Netlink
Regulatory Class: II
Product Code: GWQ
Dated: August 17, 2000
Received: August 18, 2000

Dear Mr. Brunner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **# K002570**

Device Name: **Modification to Bio-logic Ceegraph IV product for Netlink.**

Indications For Use:

The Bio-logic Ceegraph EEG product family is indicated for use in the recording and analysis of EEG tests. Typical routine EEG tests are 20-30 minutes in duration, but the Ceegraph system can also be used for longer tests, including continuous long-term EEG monitoring with patient video. In general, EEG testing is indicated for use whenever it is necessary to measure and record a patient's electrophysiological activity, including the electrical activity of the brain, by attaching multiple electrodes at various locations on the body.

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The use of the Bio-logic Ceegraph EEG family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochniak

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002570

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)